

Application No. 09/689139
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Amendment
Attorney Docket No. S63.2B-9178-US01

Remarks

Allowable Subject Matter

Claims 5, 7-10, 14, 18, 19, 22-23, 27 and 33-35 have been objected to as being dependent upon a base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim.

Applicant submits that the following arguments are sufficient to overcome the rejection of the base claim.

New Rejections

35 U.S.C. §103

Claims 1-4, 6, 11-13, 14-17, 20-21, 24-26 and 28-32 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fritz et al. (US 5,735,830). The Office Action asserts that Fritz teaches catheters (col. 1, line 14) made via the moisture-crosslinking (col. 2, line 21) of polymer compositions containing polyethylenes (col. 1, lines 63-67), silanes and peroxides (col. 2, line 17), and that the articles made are removed from the shaping tool after crosslinking (col. 4, lines 19-21).

Applicant traverses the rejection.

Claim 1 of the present application is directed to a medical device comprising a medical balloon formed from a crosslinkable polymeric material, the crosslinkable material being the reaction product of at least one polymer and at least one hydrolysable silane, the reaction product further reacted with moisture to produce a polymeric material crosslinked through --Si--O--Si-- linkages.

The Office Action admits that Fritz et al. fail to teach balloon catheters or catheter balloons, but that the examiner considers "balloon catheters", "catheter balloons", and "dilatation balloons" to be interchangeable terms, and that in the absence of convincing objective evidence to the contrary, the use of the materials and processes of Fritz et al. to make catheter balloons for use in/with catheters is deemed a matter of engineering choice.

Applicant disagrees. "Balloon catheters: are not "catheter balloons" or "dilatation balloons". Catheter balloons or "dilatation balloons" are components of "balloon catheters".

Fritz et al. state that their invention concerns a *medical instrument comprising at*

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least one shaft section having a lumen, wherein the shaft section or sections are made from a flexible polymer material. See col. 1, lines 7-10.

Applicant submits that in fact, while Fritz et al. both disclose and claim making a catheter shaft (claims 1 and 12), they fail to suggest that the balloon portion of the catheter is formed from the flexible polymer material described therein.

The shaft section of a catheter is made by extrusion. Typically the balloon portion, however, is made by first forming the polymer material into a tube by extrusion, and then further by gas pressure molding of the tube in a balloon mold.

Applicant submits that Fritz et al. do make reference to use of shaping tools, as indicated at the bottom of page 3 of the Office Action. However, shaping tools are not employed in forming medical balloons, and Fritz et al. specifically describe their use in making tubes, not for further processing of tubes into balloons. See col. 3, lines 56-64. The formation of balloons would require further processing steps not suggested by Fritz et al. Applicant submits that had Fritz et al. contemplated balloon formation, they would have specifically described balloon formation. Instead only catheter shaft sections, i.e. tubes, and their formation are described by Fritz et al.

Thus, it does not necessarily follow that a specific material, successfully employed in forming catheter tubes, can be successfully employed in making balloons. The properties which Fritz et al. deem desirable, i.e., physiologically unobjectionable, transparent, which can be sterilized by steam, and which has the necessary flexibility while maintaining a constantly open lumen (col. 1, lines 53-57), are not indicative of successful balloon formation. Consequently, Applicant submits that it would not be obvious to employ the flexible polymer material of Fritz et al., described for use in making catheter shaft sections, to form a balloon.

Applicant respectfully requests withdrawal of the rejection of claims 1-4, 6, 11-13, 15-17, 20-21, 24-26 and 28-32 under 35 U.S.C. §103(a) as being unpatentable over Fritz et al. (US 5,735,830).

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CONCLUSION

Claims 1-35 are pending in the application. Applicant has addressed each of the issues presented in the Office Action. Based on the foregoing, Applicant respectfully requests reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

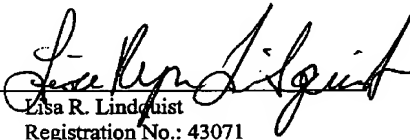
Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date:

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By:


Lisa R. Lindquist
Registration No.: 43071

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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